counts or the like. There remains an unfulfilled need for treatment for EPM-afflicted equines, particularly horses, which is effective, convenient to administer and useful for the reduction of resistant strains.

Therefore, it is an object of this invention to provide an immunogenically active component useful for the prevention or amelioration of EPM.

It is another object of this invention to provide a vaccine composition suitable for use in equines against infection and disease caused by the protozoan parasites *Sarcocystis neurona* and/or *Neospora hughesi*.

It is a further object of this invention to provide a method for the prevention or amelioration of EPM disease in equines that need such protection. Other objects and features of the invention will become apparent from the detailed description set forth herein below.

SUMMARY OF THE INVENTION

The present invention provides an immunogenically active component which comprises inactivated *Sarcocystis neurona* cells or inactivated *Neospora hughesi* cells; DNA derived therefrom; or a mixture; or in combination with other vaccine components.

The present invention further provides an immunogenically active component which comprises a member selected from the group consisting of merozoite antibody inducing, inactivated *Sarcocystis neurona* cells; tachyzoite antibody inducing, inactivated *Neospora hughesi* cells; a merozoite or tachyzoite antibody inducing antigen derived or extracted from said cells;

specification.) Additionally, it is averred that the *Sarcocystis neurona* isolate designated SNg, having ATCC Accession No. PTA-2972, has been deposited and accepted in the American Type Culture Collection under the provisions of the Budapest Treaty. It is also averred that all restrictions upon public access to the deposit will be irrevocably removed upon the grant of the patent on this application.

Applicants respectfully ask that the Examiner kindly enter the proposed amendment, albeit after a final rejection, and withdraw the rejection of the pending claims insofar as the written description requirement is concerned. The present amendment does not present any new issues requiring further consideration or search and requires only a cursory review by the Examiner. The amendment introduces no new matter into the application. Applicants previously highlighted the fact that the starting material, *i.e.*, *S. neurona*, was available and identifiable at the time of filing the application and, as a consequence, they did not realize that any amendment would be necessary. Because the Examiner did not find the prior arguments persuasive, it is now seen on Applicants' reconsideration and fresh perspective of the issues that the addition of the deposit information into the specification and the appropriate affirmations in the record may remove the necessity of appeal on this particular issue.

Moreover, under the guidelines of M.P.E.P. § 714.13, any refusal to enter the proposed amendment should not be arbitrary. The proposed amendment should be given sufficient consideration to determine whether the issues on appeal are simplified or whether the claims are in condition for allowance. In sum, Applicants hope that the Examiner will enter the amendment and reconsider the rejections of record in a new, favorable light.

To further simplify the issues on appeal by eliminating one or more of the remaining rejections of record, or perhaps provide a response that places the application in condition for an immediate allowance, additional comments will be made in traversal of the outstanding rejections as follows:

(1) The Examiner has sustained the rejection of Claims 5-8 and 10-14 as being unpatentable under 35 U.S.C. § 112, first paragraph, because the specification allegedly fails to comply with the enablement requirement. In the Examiner's opinion, the rejection is justified because the art allegedly teaches no vaccine to protect horses from parasites and the specification allegedly does not provide substantive evidence that the claimed vaccine is capable of inducing

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Replication initiates at multiple dispersed sites in the ribosomal DNA plasmid of the protozoan parasite Entamoeba histolytica.

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Genetic Engineering Unit, Jawaharlal Nehru University, New Delhi, India.

Molecular and cellular biology (UNITED STATES) May 1996, 16 (5) p2314-24, ISSN 0270-7306 Journal Code: 8109087
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In the protozoan parasite Entamoeba histolytica (which causes amoebiasis in humans), the rRNA genes (rDNA) in the nucleus are carried on an extrachromosomal circular plasmid. For strain HM-1:IMSS, the size of the rDNA plasmid is 24.5 kb, and 200 copies per genome are present. Each circle contains two rRNA transcription units as inverted repeats separated by upstream and downstream spacers. We have studied the replication of this molecule by neutral/neutral two-dimensional gel electrophoresis and by electron microscopy. All restriction fragments analyzed by two-dimensional gel electrophoresis gave signals corresponding to simple Y's and bubbles. This showed that replication initiated in this plasmid at multiple, dispersed locations spread throughout the plasmid. On the basis of the intensity of the bubble arcs, initiations from the rRNA transcription units seemed to occur more frequently than those from intergenic spacers. Multiple, dispersed initiation sites were also seen in the rDNA plasmid of strain HK-9 when it was analyzed by two-dimensional gel electrophoresis. Electron microscopic visualization of replicating plasmid molecules in strain HM-1:IMISS showed multiple replication bubbles in the same molecule. The location of bubbles on the rDNA circle was mapped by digesting with PvuI or BsaHI, which linearize the molecule, and with SacII, which cuts the circle twice. The distance of the bubbles from one end of the molecule was measured by electron microscopy. The data corroborated those from two-dimensional gels and showed that replication bubbles were distributed throughout the molecule and that they appeared more frequently in rRNA transcription units. The same interpretation was drawn from electron microscopic analysis of the HK-9 plasmid. Direct demonstration of more than one bubble in the same molecule is clear evidence that replication of this plasmid initiates at multiple sites. Potential replication origins are distributed throughout the plasmid. Such a mechanism is not known to operate in any naturally occurring prokaryotic or eukaryotic plasmid.

Tags: Research Support, Non-U.S. Gov't

ATCC

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BUDAPEST TREATY ON THE INTERNATIONAL RECOGNITION OF
THE DEPOSIT OF MICROORGANISMS FOR THE PURPOSES OF PATENT PROCEDURE

INTERNATIONAL FORM

RECEIPT IN THE CASE OF AN ORIGINAL DEPOSIT ISSUED PURSUANT TO RULE 7.3
AND VIABILITY STATEMENT ISSUED PURSUANT TO RULE 10.2

To: (Name and Address of Depositor or Attorney)

Fort Dodge Animal Health
Attn; Joseph W. Whalen Jr.
800 5th Street N.W.
Fort Dodge, IA 50501

Deposited on Behalf of: Fort Dodge Animal Health, A Division of American Home Products

Identification Reference by Depositor: Sarcocystis neurona propagated in E. Dermal cells: Sarcocystis neurona

Patent Deposit Designation PTA-2972

The deposit was accompanied by: __ a scientific description __ a proposed taxonomic description indicated above.

The deposit was received January 25, 2001 by this International Depository Authority and has been accepted.

AT YOUR REQUEST: X We will inform you of requests for the strain for 30 years.

The strain will be made available if a patent office signatory to the Budapest Treaty certifies one's right to receive, or if a U.S. Patent is issued citing the strain, and ATCC is instructed by the United States Patent & Trademark Office or the depositor to release said strain.

If the culture should die or be destroyed during the effective term of the deposit, it shall be your responsibility to replace it with living culture of the same.

The strain will be maintained for a period of at least 30 years from date of deposit, or five years after the most recent request for a sample, whichever is longer. The United States and many other countries are signatory to the Budapest Treaty.

The viability of the culture cited above was tested March 19, 2001. On that date, the culture was viable.

International Depository Authority: American Type Culture Collection, Manassas, VA 20110-2209 USA.

Signature of person having authority to represent ATCC:

Tanya Nunnally, Patent Specialist, Patent Depository

Date: March 22, 2001

BP4/9